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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ORRICK, HERRINGTON & SUTCLIFFE, LLP
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

HO, UYEN T

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,970

Applicant(s)

BETELIA ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-20 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) 38,40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9-20,37 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention: Species I: the leaflets are connected to one another by weakened regions; Species II: the leaflets are not connected to one another by weakened regions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is no generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

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case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Charles Fowler on 2/4/2003 a provisional election was made with traverse to prosecute the invention of I, claims 1, 9-20, 37 and 37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 38, 40 and 41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. (5,824,041) in view of Martinez et al. (5,453,090). Lenker et al. disclose a stent delivery system (fig. 19A-19D) including an elongate tubular outer sheath (254), a

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tubular prosthesis (P), an elongate bumper member (258) having a blunt edge disposed adjacent the proximal end of the prosthesis (P) preventing axial displacement of the prosthesis upon retraction of the elongate tubular outer sheath (254), wherein the bumper member comprising an extension (252) extending from the bumper element, the extension including a lumen for receiving a guide wire there through. Lenker et al. fail to disclose the distal of the outer sheath (254) having a size for insertion into a blood vessel and terminating in a substantially atraumatic distal portion, wherein the distal end includes a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable upon retraction of the tubular member with respect to the prosthesis to allow the leaflets to be deflected towards the open position. Martinez et al. disclose a stent delivery system including an elongate tubular outer sheath having a distal end configured to prevent trauma when inserted into a vessel, the distal end including a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable for deploying a stent (col. 4, lines 6-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a plurality of flexible leaflets as disclosed by Martinez et al. into the distal end of the tubular outer sheath of Lenker et al.'s stent delivery system in order to prevent the distal end of the outer sheath damaging the wall of a blood vessel.

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6. Claims 11-20, 37 and 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Lenker et al. '041 in view of Martinez et al. '090 further in view of Estrada et al. (6,193,686), Lodin et al. (5,460,608) and Thornton (5,891,090).

In regard to claims 11-19, 37 and 39, Lenker et al. in view of Martinez et al. disclose all the limitation of the claims except for a presence of a bumper element that includes a helical coil. Lodin et al. (fig. 1), Thornton (fig. 1) and Estrada et al. (fig. 1) disclose a catheter system including a helical coil for reinforcing the tubular catheter to prevent the tubular catheter from collapsing or breaking throughout its length and resistant to buckling or kinking. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a coil into the stent delivery system of Lenker et al. in view of Martinez in order to reinforce the bumper element and enhance the strength and pushability of the bumper element.

In regard to claim 20, it is known in the art to having a radiopaque marker on a portion of catheter, stent or any member that is inserted into a body lumen in order to track the location of the inserted member in the body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a radiopaque marker on the bumper element of Lenker et al. in view of Martinez et al.'s implant system in order to locate the bumper element in a body lumen.

7. Claims 1, 9-18, 20, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sepetka et al. (5,814,062) in view of Martinez et al. (5,453,090). Sepetka et al. disclose an implant delivery system including an elongate tubular member (4), a bumper element (26) comprising helical coil (36), and a prosthesis with a

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coiling tubular shape (28). Sepetka et al. fail to disclose the elongate tubular member having a distal end including a plurality of leaflets and the leaflets connected to each other by weakened regions. Martinez et al. disclose a implant delivery system including an elongate tubular outer sheath having a distal end configured to prevent trauma when inserted into a vessel, the distal end including a plurality of flexible leaflets being deflectable from a closed position to an open configuration and the leaflets are connected to one another by weakened regions and the weakened regions being tearable for deploying an implant (col. 4, lines 6-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a plurality of flexible leaflets as disclosed by Martinez et al. into the distal end of the tubular outer sheath of Sepetka et al.'s implant delivery system in order to prevent the distal end of the outer sheath damaging the wall of a blood vessel.

In regard to claim 20, it is known in the art to having a radiopaque marker on a portion of catheter, stent or any member that is inserted into a body lumen in order to track the location of the inserted member in the body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a radiopaque marker on the bumper element of Sepetka et al.'s implant delivery system in order to locate the bumper element in a body lumen.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cox (6,241,758) discloses a catheter including a bumper element, a tubular implant and an outer sheath with a distal end including slit.

Hieshima et al. (6,063,111) disclose a catheter including a bumper element, a tubular implant and an outer sheath.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



(Jackie) Tan-Uyen T. Ho
February 7, 2003



MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700